UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TOWN OF ANDOVER

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.;
TEVA PHARMACEUTICALS INDUSTRIES LTD.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
NORAMCO, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
CARDINAL HEALTH INC.;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
MALLINCKRODT BRAND PHARMACEUTICALS, INC.;
SPECGX, LLC;
MCKESSON CORPORATION;
AMERISOURCEBERGEN DRUG CORPORATION;
WALGREEN CO;
WALGREENS EASTERN CO.;
JONATHAN D. SACKLER;
KATHE SACKLER;
MORTIMER D.A. SACKLER;
RICHARD SACKLER;
DAVID SACKLER;
THERESA SACKLER;
ILENE SACKLER LEFCOURT;
BEVERLY SACKLER,

Civil Action No.:

COMPLAINT

(Jury Trial Demanded)

ALLERGAN PLC F/K/A ACTAVIS PLC
F/K/A ALLERGAN, INC.;
ALLERGAN FINANCE, LLC, F/K/A/
ACTAVIS, INC., F/K/A WATSON
PHARMACEUTICALS, INC.;
ALLERGAN SALES, LLC;
ALLERGAN USA, INC.;
WATSON LABORATORIES, INC.;
WARNER CHILCOTT COMPANY,
LLC;
ACTAVIS PHARMA, INC. F/K/A
WATSON PHARMA, INC.;
ACTAVIS SOUTH ATLANTIC LLC;
ACTAVIS ELIZABETH LLC;
ACTAVIS MID ATLANTIC LLC;
ACTAVIS TOTOWA LLC;
ACTAVIS LLC;
ACTAVIS KADIAN LLC;
ACTAVIS LABORATORIES UT, INC.,
F/K/A WATSON LABORATORIES,
INC.-SALT LAKE CITY;
ACTAVIS LABORATORIES FL, INC.,
F/K/A WATSON LABORATORIES,
INC.-FLORIDA;

AND

JANE DOES 1 – 50,

Defendants.

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I. PRELIMINARY STATEMENT

1. Plaintiff the Town of Andover, Massachusetts ("the Town" or "Andover"), like many other jurisdictions across the country, is struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a corporate business plan. It started with a decision by the owners and directors of Purdue Pharma L.P., Purdue Pharma, Inc., and the Purdue Frederick Co. (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for themselves. Unfortunately, their deceptive strategies were quickly joined by Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc. Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Teva Ltd., Mallinckrodt plc, SpecGX LLC, Mallinckrodt Brand Pharmaceuticals, Inc. Mallinckrodt LLC, Allergan plc f/k/a Actavis plc f/k/a Allergan, Inc.; Allergan Finance, LLC, f/k/a/ Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc., f/k/a/ Watson Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida; (collectively "Allergan"), (collectively with the Sackler Defendants "Manufacturing Defendants"), all of whom used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing

of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1] In addition, the Manufacturing Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and Walgreen Co. failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders. As a direct consequence, the rampant use, overuse, and abuse of opioids has overwhelmed much of the country, including the Town of Andover.

2. Andover, Massachusetts brings this action to redress these Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids.

3. Manufacturing Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Kadian, Norco, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

4. Distributor Defendants McKesson Corporation d/b/a McKesson Drug Company, AmerisourceBergen Drug Corporation, Walgreens Co., and Cardinal Health, Inc. distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in Andover.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—

[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. To expand their market and profits, Manufacturing Defendants initiated, and for years have maintained, a deceptive marketing scheme that was intentionally designed to, and effectively did, change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. To convince doctors and patients that opioids can and should be used to treat chronic pain, these Defendants had to convince them that long-term opioid use is both safe, by minimizing and understating the risks, especially the serious risk of addiction, and helpful, by overstating the benefits, especially the serious risk of addiction.

7. Manufacturing Defendants use both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. In this way, they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles.

8. Manufacturing Defendants had control over the information they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Manufacturing Defendants created a population of addicted patients who sought opioids at

never-before-seen rates. The scheme worked, and through it the Manufacturing Defendants' profits soared as more and more people became dependent on opioids.

9. In addition, Mallinckrodt's and Janssen's vertically integrated business models enabled them to profit from the opioid crisis the nation now confronts to an even greater extent. Both Mallinckrodt and Janssen have supplied, and upon information and belief, continue to supply, raw opium or "active pharmaceutical ingredients" (known as "APIs") to themselves and to other manufacturers. In fact, as Purdue was developing OxyContin, Janssen worked in 1994 to create a "high thebaine" poppy to meet anticipated demand. Internally, Janssen described the result of the project, known as the "Norman" poppy, as a "transformational technology that enabled the growth of oxycodone."

10. Once Manufacturing Defendants created the mass market for opioids they worked together with McKesson, Cardinal, AmerisourceBergen, and Walgreens (collectively, "Distributor Defendants") to flood it. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

11. Wholesale distributors buy prescription drugs, including narcotics, from manufacturers at enormous volumes and sell them to pharmacies. This allows pharmacies to quickly obtain a full range of prescription drugs from a single source, without having to manage relationships with multiple manufacturers. With distribution centers across the country, distributors offer "just-in-time delivery," ensuring that pharmacies can provide the drugs their customers need, without the expense and risk of excess inventory. Like other brokers, distributors

earn their profits based on the spread between their buy and sell prices, as well as manufacturer chargebacks and a fee that is a percentage of sales. As discussed further below, they have financial incentives to keep the volume of controlled substances they distribute high, and to fill orders and supply customers despite red flags of diversion.

12. With their central location in the healthcare marketplace, Distributor Defendants also have a treasure trove of information, such as data and services, which they sell upstream to manufacturers and downstream to pharmacies to further leverage their profits. Defendants could have used this information to ensure they were providing opioids only to a legitimate market, but did not. Because of the addictive nature of these drugs and the existence of a black market for their use, however, wholesale distributors have long-standing duties, as described further below, to ensure that the controlled substances they supply, including opioids, are managed and monitored to ensure they reach only a legitimate market and are not diverted for illicit use.

13. Manufacturing Defendants also failed to control their supply of opioids. They did so even though they, too, had particularly detailed information about the distribution and sale of opioids throughout the country, including in the Town of Andover. This included information concerning prescriptions of their drugs such as chargeback data, which provided essentially real time information about opioid prescriptions for their products, and the observations of their sales forces on the ground, who were well-positioned to identify suspicious activity. Each of the Manufacturing Defendants manufactured, marketed, and sold opioids without an adequate system in place to prevent diversion of its opioids or to investigate, report, and refuse to fill orders that it knew or should have known were suspicious.

14. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care setting struggles with addiction. In 2014, almost 2 million Americas were

addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

15. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. However, prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

16. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including the Town of Andover, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[2] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or simply could not afford prescription opioids.

17. Thus, rather than compassionately helping patients, as manufacturing defendants deceptively suggested increased opioid prescribing would do, this explosion in opioid use and Defendants' profits has come at the expense of patients and has caused ongoing harm and damages

[2] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

to the Town of Andover. As the former CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[3]

18. Defendants' conduct has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing or paying for addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

19. The burdens imposed on the Town are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

20. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

21. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

22. The Town of Andover brings this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

[3] *Id.*

II. PARTIES

A. Plaintiff

23. The Town of Andover is located in Essex County, Massachusetts. Pursuant to M.G.L. c. 40 §§ 1 and 2, it has the authority to prosecute suits on behalf of the Town.

B. Defendants

24. Former Purdue directors Jonathan D. Sackler, David Sackler, Kathe A. Sackler, M.D., Mortimer D.A. Sackler, Theresa Sackler, Beverly Sackler, Ilene Sackler Lefcourt, and Richard S. Sackler, M.D., ("the Sackler Defendants,") all authorized, ordered, and are responsible for the acts of Purdue described herein. Each acted and failed to act in ways that led to and furthered Purdue's wrongdoing. Purdue, a privately held company owned by the Sackler family, manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in Andover.[4] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids. Purdue filed for Chapter 11 bankruptcy protection on September 15, 2019.[5]

25. Jonathan D. Sackler is a former director of Purdue and a resident of Connecticut. He served on the Board of Purdue Pharma Inc. from 1990 until 2018. He was a Senior Vice President of Purdue from 2000 until 2003. Through his decisions and directives, Defendant Jonathan Sackler knowingly caused the promotion and sales of Purdue opioids in Andover from

[5] Purdue is not named as a defendant herein because of the bankruptcy stay. However, the Town reserves all rights to proceed against Purdue in the event the stay is lifted, and is proceeding against the Sackler Defendants who owned, directed, and controlled the actions of Purdue.

the sales messages passed directly to Andover area prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Andover area prescribers by Purdue. Defendant Jonathan Sackler directed the many actions taken through Purdue detailed in this Complaint. Jonathan Sackler is an owner of the Purdue entities, which are privately owned companies, and greatly benefited from these entities.

26. Kathe A. Sackler, M.D., is a former director of Purdue and a resident of Connecticut. She was a member of the Purdue Pharma Inc. board of directors from 1996 until September 2018, and of The Purdue Frederick Company's board until March 2005. She was a Senior Vice President of Purdue Pharma L.P. and Purdue Frederick Inc. from December 1999 to May 2007, and a Vice President of the Purdue Frederick Company from April 1994 until March 2005. Through her decisions and directives, Defendant Kathe Sackler knowingly caused the promotion and sales of Purdue opioids in Andover from the sales messages passed directly to Andover area prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Andover area prescribers by Purdue. Defendant Kathe Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant Kathe Sackler is an owner of the Purdue entities and greatly benefited from them.

27. Mortimer D.A. Sackler is a former director of Purdue and a resident of New York. He served on the Board of Purdue Pharma Inc. from 1993 until 2018. He was a Vice President of Purdue from 1999 until 2003. Through his decisions and directives, Defendant Mortimer Sackler knowingly caused the promotion and sales of Purdue opioids in Andover from the sales messages passed directly to Andover area prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Andover area prescribers by Purdue. Defendant Mortimer

Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant Mortimer Sackler is an owner of the Purdue entities and greatly benefited from them.

28. Richard S. Sackler, M.D. was the Co-Chairman of Purdue Pharma Inc.'s board from 2003 until May 2007, and a member of Purdue Pharma Inc.'s board from 1990 until July 2018. He was on the board of The Purdue Frederick Company from 1990 until March 2005. He additionally held managerial roles at Purdue, first joining the company in 1971 as an assistant to his father, Raymond. He became Vice President of the Medical Department in 1984, and at other times oversaw the Sales & Marketing Department. He was President of Purdue from 1999 to 2003; and Senior Vice President of the Purdue Frederick Company until March 2005. He resides in Florida. Defendant Richard Sackler, upon information and belief, has long held an ownership interest in Purdue and continues to hold such an ownership interest. Through his decisions and directives, Defendant Richard Sackler knowingly caused the promotion and sales of Purdue opioids in Andover from the sales messages passed directly to Andover area prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Andover area prescribers by Purdue. Richard Sackler is the listed inventor on a number of patents assigned to Purdue, including U.S. Patent 9,3861,628, *Buprenorphine-Wafer for Drug Substitution Therapy* (January 9, 2018), a patent issued, *inter alia*, to Sackler and assigned by Sackler and his co-inventors covering a drug for "drug substitution therapy in drug-dependent human subjects." In other words, having caused the opioid epidemic, Sackler, through his companies, is poised to profit off of its abatement. Defendant Richard Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant Richard Sackler is an owner of the Purdue entities and greatly benefited them.

29. David Sackler, son of Defendant Richard Sackler, is a resident of New York, and was Purdue Board member from July 2012 until August 2018. David Sackler currently works for a hedge fund, Moab Capital Partners, LLC, which he co-founded. Through his decisions and directives, Defendant David Sackler knowingly caused the promotion and sales of Purdue opioids in Andover from the sales messages passed directly to Andover area prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Andover area prescribers by Purdue. Defendant David Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant David Sackler is an owner of the Purdue entities and greatly benefited from them.

30. Defendant Ilene Sackler Lefcourt is the daughter of Purdue founder Mortimer Sackler, Sr., and sister to Defendants Kathe and Mortimer Sackler. She is a resident of New York and was one of the original Purdue board members from 1990, and left the board in 2018. Defendant Ilene Sackler Lefcourt directed the many actions taken through Purdue detailed in this Complaint. Defendant Ilene Sackler Lefcourt is an owner of the Purdue entities and greatly benefited from them.

31. Defendant Theresa Sackler, widow of Mortimer Sackler, Sr., is a resident of the United Kingdom, where she is a Trustee of the Victoria and Albert Museum. Theresa Sackler joined the Purdue board in 1993 and stepped down from the board in September 2018. Defendant Theresa Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant Theresa Sackler is an owner of the Purdue entities and greatly benefited from them.

32. Defendant Beverly Sackler is the widow of Purdue founder Raymond Sackler and resides in Connecticut. She became a Purdue board member in 1993 and left the board in October 2017. She is also the former Director and Treasurer of the Raymond and Beverly Sackler

Foundation, Inc., which is registered to do business and conducts medical research in Massachusetts. Defendant Beverly Sackler directed the many actions taken through Purdue detailed in this Complaint. Defendant Beverly Sackler is an owner of the Purdue entities and greatly benefited from them.

33. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including Andover. Teva USA also sells generic opioids throughout the United States and Andover, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd. (Teva Ltd.), Teva USA's parent company based in Israel, acquired in August 2016. Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon are collectively referred to as "Teva."

34. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in Andover. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

35. The close connection between Teva Ltd. and its U.S. subsidiaries, as well as the blurred distinction between them, is shown in Teva's websites. For example, on Teva USA's

website is a page entitled "Teva Pharmaceutical Industries Limited," on a page labeled "intended for US residents only," which includes the following: "Teva improves health in the US every day, every minute, every second. One in every six prescriptions dispensed in the US is a Teva product. Approximately 22 prescriptions in the US are filled by Teva products every second....Teva is the world's largest maker of generic pharmaceutical products."[6] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales . . . ." [7] The United States is the largest of Teva Ltd.'s global markets, and it represents nearly half of its total revenue.[8]

36. Other publicly available information demonstrates Teva Ltd.'s control over Cephalon's operations: For example, immediately after acquiring Cephalon, Teva Ltd. caused Cephalon to increase its product prices up to twenty-five percent.[9] The two companies combined sales forces,[10] product pipelines, and research and development efforts.[11]

37. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen

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[6] https ://www.tevausa.com/Company. aspx

[7] New Yorker; Fact Sheet Teva Pharmaceutical Industries Ltd. Annual Report (Form 20-F) (Feb. 12, 2013) at 62.

[8] *Id*. at 62-64.

[9] Tracy Staton, *Teva jacks up prices on Cephalon legacy brands* (Dec. 7, 2011), http://wwW.fiercepharma.com/story/tevajacks-prices-cephalon-legacy -brands/2011 -12-07.

[10] *NASDAQ OMX 27th Investor Program Conference Call,* Teva Pharm. Indus. Ltd. (Dec. 6, 2011, 5:15 AM), http ://seekingalpha.com/article/315684-teva-pharmaceuticals-management-presents-at-nasdaq-omx-27th-investor-program-transcript?page=4.

[11] *See generally, Teva Pharmaceuticals Industries ' Management Presents at Citi Global Health Care Conference (Transcript)* (Mara 8, 2012), http://seekingalpha.com/article/419471-

Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

38. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware with offices in Athens, Georgia and Schaffhausen, Switzerland. Noramco was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital Partners LP, a limited partnership incorporated in Delaware.

39. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

40. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

41. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica, and Noramco (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally (including the API for opioids). Among the drugs Janssen manufactures or manufactured are: Duragesic, Nucynta, and Nucynta ER.[12] Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Dr. Paul Janssen invented fentanyl,

[12] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

the drug in Duragesic, in the 1950s.[13] After Janssen began the deceptive marketing campaign described in this complaint, and prior to 2009, Duragesic reached at least $1 billion in annual sales.

42. Prior to 2016, Janssen also had a global Active Pharmaceutical Ingredients manufacturing network for opioids and was among the largest narcotic API suppliers in the United States. The two subsidiaries through which it carried out this business, Noramco and Tasmanian Alkaloids, were considered part of its "pain management franchise."[14] Tasmanian Alkaloids created, manufactured and patented a new, more potent strand of poppy (high thebaine) and delivered it via intercompany transfer to Noramco. Both Noramco and Tasmanian Alkaloids are part of the J&J Family of Companies,[15] operating in a backward integration model to control the supply chain of opioid materials for production of "high-purity controlled substances."[16] Noramco steadily gained U.S. market share and capitalized on brand to generic switches. Through these subsidiaries, Janssen supplied opioid APIs, including oxycodone, hydrocodone, and fentanyl, to Teva and other drug manufacturers in the United States.[17]

43. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It

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[13] Judgment after Non-Jury Trial, *State of Oklahoma, ex rel. Mike Hunter, Attorney General of Oklahoma v. Purdue Pharma L.P. et al.*, Case No. CJ-2017-816, at 5 (Dist. Ct. Cleveland Cnty., Okla. Aug. 26, 2019) (hereinafter "Oklahoma Judgment after Non-Jury Trial")

[14] *Id.*

[15] https://www.noramco.com/our-capabilities/

[16] Backward integration is "a form of vertical integration in which a company expands its role to fulfill tasks formerly completed by businesses up the supply chain." https://www.investopedia.com/terms/b/backwardintegration.asp (Last visited: May 21, 2019).

[17] Oklahoma Judgment after Non-Jury Trial at 5.

governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

44. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

45. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

46. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in Andover. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Andover, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would

stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent.

47. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to do business in Massachusetts. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt plc. Defendant SpecGx LLC, Inc. is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt LLC. Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals and SpecGx LLC are referred to as "Mallinckrodt."

48. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its opioid products with its own direct sales force.

49. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for the controlled substances that it manufactures.[18] Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

50. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

51. Defendant Allergan plc (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly-owned

[18] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm

subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

52. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share. *See City of Chicago v. Purdue Pharma L.P.*, et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7. Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions. *See id.* Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date." *See City of Chicago v. Purdue Pharma L.P.*, et al. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.

53. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

54. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco.[19] Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

55. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

56. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

57. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

[19]The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

58. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

59. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

60. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

61. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was

sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

62. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

63. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

64. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

65. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic

businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

66. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

67. Each of these defendants and entities currently is or was previously owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

68. Actavis manufactures or has manufactured brand named opioids Kadian and Norco as well as generic versions of Kadian, Duragesic, and Opana in the United States.

69. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. The Town alleges

the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Andover.

70. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in Andover. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

71. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Andover. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

72. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

73. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Andover. It has a distribution center in Mansfield, Massachusetts. AmerisourceBergen is the eleventh largest

company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

74. Collectively Cardinal, McKesson and AmerisourceBergen are, at times, referred to herein as "The Big Three."

75. Walgreen Co ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Andover and throughout the country. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the country which distribute medications, including opioids, to various states, including Massachusetts. Walgreens Eastern Co. distributed opioids into Massachusetts. Walgreens is registered to do business in Massachusetts under the name Walgreens of Massachusetts, LLC.

76. Collectively Cardinal, McKesson, AmerisourceBergen, and Walgreens are at times referred to herein as "Distributor Defendants."

77. The Distributor Defendants dominate the wholesale distribution market, including in the Town.

78. For Defendant Jane Does 1 – 50, Andover lacks sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The Town will amend this Complaint to show their true names when they are ascertained.

III. JURISDICTION AND VENUE

79. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because the Town's claim under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.* ("RICO") raises a federal question. This Court has supplemental

jurisdiction over the Town's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

80. Venue is proper in this court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the United States District Court for Massachusetts.

81. This court has personal jurisdiction over Defendants pursuant to M.G.L. c. 223A §3 because they transact business in the Commonwealth of Massachusetts, contract to supply goods and manufactured products in the Commonwealth of Massachusetts, carry on a continuous and systematic part of their general businesses within Massachusetts, including in the Town of Andover, have transacted substantial business with Massachusetts and the Town of Andover's entities and residents, and have caused grave harm in the Town as a result.

82. This Court has personal jurisdiction over the Sackler Defendants because they authorized, ordered, and through Purdue, committed tortious acts in Andover by authorizing and directing Purdue's false and deceptive marketing described herein, and by approving budgets advancing Purdue's deceptive promotional activities in Andover which harmed the Town and its residents.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

83. As explained further below, Manufacturing Defendants promoted their branded opioids and opioids generally, in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement and other purported benefits of opioids. They conveyed these deceptive messages to prescribers through sales representatives, patient guides, purportedly educational programs, branded and unbranded websites, and other marketing materials. They also disseminated deceptive messages through third party patient

advocacy groups and professional associations who were financially tied to Manufacturing Defendants but seemed independent and, therefore, credible. Manufacturing Defendants distributed these messages, or facilitated their distribution in the Andover area, with the intent that prescribers and/or consumers would rely on them in choosing to use opioids in general, and their opioids specifically, to treat chronic pain.

84. Manufacturing Defendants deceptive claims were particularly insidious because they often targeted prescribers, such as primary care physicians, who were among those who were the least likely to have the training and experience to evaluate both the marketing with which they were targeted and patients' pain conditions. [20] As Dr. Lynn Webster, one of Teva and Mallinckrodt's own "Key Opinion Leaders" has since acknowledged: "Physicians were ill prepared to address pain. They were even less prepared to use opioids. I had no training about addiction when I was in medical school or in my residency program. Most physicians still do not have hardly any knowledge about how to treat addiction, except for alcoholism."[21] He "[did not] think doctors read the [drug] labels."[22] And, he further acknowledged that pharmaceutical companies are partly to blame for the opioid crisis; he understood their motivation as well, noting, "they're a business, so they wanted to influence prescribing."[23]

85. Manufacturing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who

[20] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

[21] OK Webster Dep. Tr. 124:13-126:20

[22] OK Webster Dep. Tr. 431:8-20

[23] OK Webster Dep. Tr. 124:13-126:20 & 254:1-8.

expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

86. Upon information and belief, based on Manufacturing Defendants' own marketing strategy and messages, industry's efforts to learn of competitors' strategies and to survey prescribers and patients regarding their perceptions of their drug products, Manufacturing Defendants were aware that health care providers and patients misperceived the risks and benefits of opioids for chronic pain. Indeed, that was their goal, and Manufacturing Defendants' internal analysis of the success of their efforts also would have put them on notice that they were receiving the return on investment they sought. This awareness obligated Manufacturing Defendants to ensure that prescribers and patients had accurate information about the risks and benefits of their products, consistent with their product labels. In other words, in selling their products into a market that they knew was distorted by (and extended and sustained through) fraud, including their own deceptive marketing, Manufacturing Defendants had a duty to clearly community the risks, warnings, and indications contained in their own product labels to ensure that their drugs were used appropriately and safely.

87. Moreover, Teva, Allergan, and Mallinckrodt also deceptively and unconscionably marketed their generic opioids, and Janssen, too, engaged in unbranded promotion. Manufacturing Defendants' branded and unbranded marketing benefited the sales of their generic products and APIs, too. Increasing the market for their branded opioids and building a market for opioids generally would, necessarily, increase sales of generic opioids and bolster their API business.

A. Manufacturing Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

88. Manufacturing Defendants rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits

frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[24] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

89. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturing Defendants directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief,[25] their sales forces in Massachusetts, including in the Andover area, carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

90. Manufacturing Defendants were aware of the strength of their in-person marketing. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a

[24] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

[25] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Andover in the same manner as elsewhere.

2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

91. Manufacturing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturing Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

92. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturing Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites.

93. Neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Manufacturing Defendants' sales representatives, were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). Upon information and belief, all of the messages described below were disseminated to Andover area prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources that were a part of the Manufacturing Defendants' nationwide marketing efforts.

1. Manufacturing Defendants Minimized or Mischaracterized the Risk of Addiction

94. To convince prescribers and patients that opioids are safe, Manufacturing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids. Manufacturing Defendants have never acknowledged, retracted, or corrected these misrepresentations.

95. Manufacturing Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. In addition, Manufacturing Defendants' sales representatives failed to disclose the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

96. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. For example, *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

97. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue widely distributed *Providing Relief, Preventing Abuse* to physicians through direct mailings to physicians, and made it available to sales representatives to show to or leave with prescribers.

98. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically

align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

99. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

100. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[26]

101. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven

[26] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

102. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

103. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

104. As part of its strategy, Janssen trained its sales representatives to use "emotional selling" for opioids by convincing physicians that undertreated pain was harming patients,[27] while also promoting opioids as the solution. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." This guide is still available online.

105. Janssen also relied on the same "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980 as did Purdue. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients

[27] Oklahoma Judgment at 10.

treated with opioids.[28] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if no sign of addiction was noted in the patients records.

106. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[29]

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

107. Although Janssen used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick. Still, "Janssen's marketing materials repeatedly used the Porter and Jick letter . . . in deceptive ways to support misleading claims that downplay the risk of addiction and overstate the efficacy of opioids."[30]

[28] Jane Porter & Herschel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[29] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 174 (Rodale 2003).

[30] Oklahoma Judgment in a Non-Jury Trial at 14.

108. The enormous impact of the misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . . [31]

109. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[32]

110. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." (Although Janssen has described the website as an unbranded third-party program, it carried Janssen's trademark and copy was approved by Janssen.)

111. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

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[31] Pamela T.M. Leung, B.Sc. Pharm., *et al.*, *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194, 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150.

[32] Marilynn Marchione, Assoc. Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

112. A Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[33]

113. Teva sponsored and facilitated the development of a guidebook, Opioid Medications and REMS: A Patient's Guide, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

114. In addition, a 2003 Teva-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

115. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are

[33] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Mgmt.*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last updated July 2, 2015).

evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[34]

116. The FAQs section of pain-topics.org contained misleading information about pseudoaddiction, discussed further below. Specifically, the website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [35]

117. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[36] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

118. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused

[34] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php, (Last visited March 2, 2018.)

[35] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance (Last visited March 2, 2018.)

[36] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!* . The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."

c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

d. "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."

e. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

f. "[I]n our experience, the issue of tolerance is overblown."

g. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

h. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

i. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

j. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken

daily and no addiction."

This book is still available online in Andover and elsewhere.

119. Mallinckrodt's former parent Company, Covidien, published a patient resource, "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

120. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

121. Actavis's detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

122. In sum, each of the Manufacturing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims.

123. In fact, studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of . . . addiction"—"even at recommended doses"—of all opioids."[37] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[38] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[39] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

124. Indeed, Mallinckrodt would have been particularly aware of opioid abuse and diversion. Mallinckrodt is the world's largest manufacturer of methadone and has been selling its own branded methadone product for the treatment of opioid addiction for decades. Thus, not only was Mallinckrodt aware of the addictiveness of opioids, but also, it has turned a profit on both perpetuating and treating the opioid crisis.

125. Similarly, Janssen also, ironically, profited from the rising addictions and abuse of opioids by suppling API for use in Naloxone for overdose and abuse, and in Naltrexone and Buprenorphine for opioid addiction.

2. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

[37] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[38] CDC Guideline at 2.

[39] *Id.* at 21.

126. Manufacturing Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

127. Purdue, through its unbranded imprint *Partners Against Pain*[40], promoted pseudoaddiction through at least 2013 on its website.

128. The Federation of State Medical Boards ("FSMB"), a trade organization representing Massachusetts state medical board as well as others, finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction" teaching that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

129. *Responsible Opioid Prescribing* was sponsored by Manufacturing Defendants, including Teva and Mallinckrodt. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more

[40] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Andover.

130. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

131. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

132. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

133. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]patients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[41] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[42]

3. Marketing Defendants Falsely Suggested that the Risk of Addiction Could

[41] CDC Guideline at 13.

[42] *Id.* at 25.

be Easily Identified and Managed.

134. Manufacturing Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants, advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturing Defendants undermined general concerns or warnings regarding addiction by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

135. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences nationwide.

136. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

137. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.* The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with

opioids.

138. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

139. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

140. Through the C.A.R.E.S. Alliance, Mallinckrodt offered a "Fact Sheet" with various "Physician Tools," including "risk assessment tools." These included the "Opioid Risk Tool," created by prominent opioid advocate Dr. Lynn Webster, whom Mallinckrodt relied on as a KOL. The "Opioid Risk Tool" is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction.

141. Versions of Dr. Webster's ORT appear on, or are linked to, websites run by Janssen.

142. Manufacturing Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

143. Further, the CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation

strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[43]

B. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use

1. Mischaracterizing the benefits and evidence for long-term use

144. To convince prescribers and patients that opioids should be used to treat chronic pain, Manufacturing Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[44] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[45] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[46] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and

[43] CDC Guideline at 28 (emphasis added).

[44] *Id.* at 10.

[45] *Id.* at 9.

[46] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

only after prescribers have exhausted alternative treatments.

145. Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

146. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturing Defendants. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

147. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

148. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and

concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

149. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

150. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

151. Manufacturing Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even

acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[47] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[48] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

152. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

153. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

154. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was

[47] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[48] *Id.*

not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[49] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

155. For example: Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

156. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

157. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

158. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

[49] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

159. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

160. Upon information and belief, Manufacturing Defendants also claimed to Town doctors—without evidence—that long-term opioid use would help patients resume their lives and jobs.

161. Manufacturing Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the Town, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

162. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug

would provide long-term pain-relief and functional improvement.

163. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[50] Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009)—which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

c. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Mallinckrodt, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

d. Teva and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

e. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

f. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

[50] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

g. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

163. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

164. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[51] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

[51] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

165. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[52] The FDA and other federal agencies have made this clear for years.[53] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[54] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[55] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[56]

166. The 2016 CDC Guideline was not the first time a federal agency publicly repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described herein, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience … results in any overall positive impact on a patient's work, physical and mental

[52] *Id.* at 20.

[53] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See*, Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[54] CDC Guideline at 2.

[55] *Id* at 18.

[56] *See* n. 23, *supra*.

functioning, daily activities, or enjoyment of life."[57] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

167. In materials Manufacturing Defendants produced, sponsored, or controlled, Manufacturing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

3. Omitting or mischaracterizing adverse effects of opioids

168. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[58] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-

[57] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm

[58] *See* n. 463, *supra*.

traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

169.Teva and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[59] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

170.Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013. *Overview of Management Options* again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. The Sackler Defendants were instrumental in pushing sales at higher doses. In a 2008 message from Dr. Richard Sackler to other members of Purdue management, and copying Defendants Jonathan and Mortimer Sackler, he wrote that he wanted to measure sales performance by strength, "giving higher measures to higher strengths." Richard Sackler, with the knowledge of Jonathan and Mortimer, sought to incentivize sales representatives to encourage higher doses and, by so doing, pad Purdue's profits, disregarding the elevated risks of addiction and overdose this strategy created for Purdue's patients.

171.Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). These Defendants deceptively describe the risks from NSAIDs while

[59] The higher figure reflects deaths from all causes.

failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

172.These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[60]

173.Again, Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

C. Manufacturing Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

174.Each manufacturing defendant falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased opioid's risks, including the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice a day, despite knowing that OxyContin frequently did not provide 12 hours

[60] Meredith Noble M, *et al*., *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

of relief to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

175.Purdue-sponsored publications and CMEs available nationwide, including in the Town, also misleadingly suggested that higher opioid doses carried no added risk. Though at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would. *A Policymaker's Guide*, the 2011 publication on which Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids.

176.Through the website pain-topics.org, Mallinckrodt claimed that there is no ceiling dosage for opioids, and that doctors may titrate up until a patient finds relief. The website does not disclose the dangers associated with higher doses, but claims that risks associated with opioids, such as death, overdoses and accidents, occur when patients do not take opioids as prescribed, or when the patient is taking other drugs or substances unknown to the prescribing doctor.

177.Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

178.Teva sponsored APF's *Treatment Options: A Guide for People Living with Pai*n (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.

179.Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage

limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

180. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

181. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[61] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[62]

D. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It did Not

[61] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[62] CDC Guideline at 16.

182.To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

183.These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end of dose failure is not more frequent dosing but higher doses—which pose greater risks.

184.OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing.

185.Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

186.From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the

dosing period.

187.Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

188.End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[63] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

189.Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage." Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of

[63] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in Andover.

190.Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.

191.Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[64]

E. Purdue and Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

192.Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution

[64] CDC Guideline at 16.

to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—and thereby prolonged the opioid epidemic in Andover.

1. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

193.Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

194.It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

195.Upon information and belief, Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis to prescribers in the Town.

196.Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue

detailers:

a. Claimed that Purdue's ADF opioids *prevent* tampering and that its ADF products could not be crushed or snorted.

b. Claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion.

c. Asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. Failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

197. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

198. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[65] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug.

199. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important

[65] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

200.The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[66] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death." [67]

201.In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[68] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

202.Yet despite the qualifying language in Purdue's label and its own evidence—and lack

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[66] CDC Guideline at 22. (emphasis added).

[67] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[68] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's deceptive marketing of reformulated Opana ER

203. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

204. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

205. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana

ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

206.Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[69] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[70]

207.Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[71]

208.In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when

[69] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[70] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[71] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

209.Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure.[72] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

210.Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in Massachusetts that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

211.Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER

[72] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

212.In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[73] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[74] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[75]Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of

[73] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[74] *Id.*

[75] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report and Terminate Suspicious Orders

213. The Manufacturing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

214. For over a decade, as the Manufacturing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

1. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

215. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

216. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying the Andover area with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to the Town.

217. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

218. Third, Defendants violated their statutory obligations under Massachusetts law and federal law. Defendants are all required to register as either manufacturers or distributors pursuant to Massachusetts law (*e.g.*M.G.L. c. . 94C § 7(a)), and federal law (21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74). Federal regulations issued under the CSA are incorporated into Massachusetts law pursuant to M.G.L. c.94C § 12(a)(2).

219. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

220. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

221. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class [of each drug] by all manufacturers;

c. Trends in the national rate of disposal of the basic class [of drug];

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

222. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

223. To ensure that even drugs produced within quota are not diverted, Federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike,

"design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

224. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

225. These requirements are also adopted and incorporated into Massachusetts law. M.G.L. c. 94C § 12(a)(2) (stating that as a registrant or licensee of Schedule II controlled substances, Distributor Defendants had a duty to comply with all applicable 'federal, state, and local laws and regulations.').

226. As wholesale drug distributors of controlled substances, Distributor Defendants were required to register with the Massachusetts Commissioner of Public Health. M.G.L. c. 94C § 7(a).

227. The Massachusetts Controlled Substances Act also requires that drug wholesalers must have "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels." M.G.L. c. 94C § 12(a)(1).

228. Massachusetts regulations, by virtue of requiring wholesale drug distributors who deal in controlled substances to register with the Massachusetts Commission of Public Health, and stating that such distributors maintain compliance with all applicable state, local laws, further mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority. M.G.L. c. . 94C § 12(a)(2). Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems.

229. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

230. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several

responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

231. Massachusetts and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor and Manufacturing Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

232. Further, these laws and industry guidelines make clear that the Distributor Defendants and Manufacturing Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

233. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For

example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, the Big Three have a unique insight into the ordering patterns and activities of their dispensing customers.

234. Like the Big Three, Walgreens is also uniquely positioned to know the ordering patterns and activities of its dispensing customers due to its role as both a distributor and a national retail pharmacy. As a national retail pharmacy, Walgreens had a vertically integrated model, which placed it in a unique role, as it had both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the

CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

235. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

236. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

237. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or 8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

238. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

239. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by Walgreens itself. That data allows it to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of

prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[76] The majority of pharmacies sell these records.[77]

240. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

241. Manufacturing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturing Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturing Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

[76] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[77] *Id.* at 389.

242. Defendants have a duty to, and are expected to, be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

243. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

2. Defendants Understood the Importance of Their Reporting Obligations

244. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

245. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

246. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor

these sales and report suspicious orders to DEA."[78] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

247. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturing Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[79] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[80]

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[78] https://www.justice.gov/usao-edmi/press-release/file/986026/download

[79] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[80] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

248. The DEA also repeatedly reminded the Defendants of their obligations under federal law, mirrored in and incorporated by Massachusetts law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[81] The Big Three Distributor Defendants have each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

249. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[82] The DEA's September 27, 2006 letter also expressly reminded them that

[81] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[82] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The

registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[83] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[84]

250. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[85] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[86]

251. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers'

purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[83] *See id.*

[84] *See id.*

[85] *See* 2007 Rannazzisi Letter.

[86] *See id.*

trustworthiness. For example, DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,[87] which suggests that distributors examine:

- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of goods to its customers (e.g., over-the-counter drugs, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?
- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?
- Does the pharmacy serve out of state customers?

[87] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/; *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

- Does it serve pain clinics?

- Are there particular practitioners who constitute most of the prescriptions it fills and who are these practitioners?

- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.

252. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[88]

253. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[89]

254. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious

[88] *See* 2017 Mallinckrodt Memorandum of Agreement ("MOA").

[89] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[90]

255. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers
>
> ii. detect and report to the DEA orders of unusual size and frequency;
>
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
>
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

[90] *Id*.

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[91]

256. In connection with that settlement, Mallinckrodt admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[92] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[93]

257. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the

[91] 2017 Mallinckrodt MOA at 2-3.

[92] *Id.* at 1.

[93] *Id.*

standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[94]

258. Mallinckrodt also acknowledged it had other information that would have alerted it to potential diversion. Specifically, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the settlement, Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[95]

259. Further, the Sackler Defendants were aware of the abuse and diversion of OxyContin but took little meaningful action to address it. Purdue's Board, which included the Sackler Defendants, was informed that from second quarter 2007 until second quarter 2008, Purdue received over 3,200 Reports of Concern but only 109 field inquiries were conducted in response. Despite being aware of tips to Purdue's compliance hotline and Reports of Concern, Purdue, under the direction of the Sackler Defendants failed to report this potential diversion to authorities, or to take other meaningful steps to prevent and address the diversion of its opioids.

[94] *Id.* at 3-4.

[95] 2017 Mallinckrodt MOA at 5.

3. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

260. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

261. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

262. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, and Walgreens:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;"

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California;

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 Walgreens MOA") with the DEA in relation to its San Diego facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations;"

j. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On September 14, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida;

l. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve the DEA's investigations. It also entered into another Memorandum of Agreement with the DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA;

m. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

263. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that timeperiod. These quantities alone are sufficient to show that Distributor Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

264. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[96] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were

[96] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[97] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers".

265. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[98] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion;" had a "[p]attern of raising thresholds arbitrarily;" "[f]ailed to review orders or suspicious activity;" and "[i]gnored [the company's] own procedures designed to prevent diversion."[99] The Washington Court House distribution center was among the warehouses investigators found "were supplying pharmacies that sold to criminal drug rings."[100]

266. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the

[97] *Id.*

[98] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[99] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[100] *Id.*

DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[101]

267. In short, McKesson was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[102] Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before."[103] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[104] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[105]

268. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die."[106] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

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[101] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[102] *Id.* (alteration in original).

[103] *Id.* (quoting a March 30, 2015 DEA memo).

[104] *Id.*

[105] *Id.*

[106] Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. Thats exactly what they did.[107]

269. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[108] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[109]

270. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

271. For example, Cardinal's former Executive Chairman, George Barrett, denied that **"**volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious

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[107] *Id.*

[108] *Id.*

[109] *Id.*

orders, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

272. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

273. Further, as referenced above, Walgreens has also been repeatedly penalized for its illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Walgreens.

274. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

275. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations

of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.[110]

276. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

277. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[111]

278. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities. [112]

[110] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[111] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

[112] *Id*.

279. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[113]

280. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

281. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

282. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[114]

[113] *Id*.

[114] *Id*.

283. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

284. Moreover, Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[115]

[115] Meier, *Pain Killer*.

285. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[116] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[117] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

286. Manufacturing Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. These Defendants did identify doctors who were their most prolific prescribers, but not to report them - to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

287. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted

[116] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

[117] *Id.*

in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[118]

288. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

G. Defendants Worked Together To Sustain Their Market and Boost Their Profits

289. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

[118] Meier, *Pain Killer*, at 179.

290. Distributor Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

291. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturing Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"), to safeguard the market for opioids and the distribution of opioids.[119]

292. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[120] All of the Manufacturing Defendants were members as well.[121]

293. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

294. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences as an

[119] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[120] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[121] https://www.healthcaredistribution.org/about/membership/manufacturer

opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[122] The conferences also gave the Distributors and Manufacturing Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[123] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

295. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or

[122] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, *available at* https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on Sept. 14, 2017).

[123] *Id*.

> technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[124]

296. The Distributor Defendants and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" Upon information and belief, the Manufacturing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

297. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[125] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

298. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS

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[124] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

[125] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Distributor Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

299. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

300. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

301. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between

proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

302. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

303. Upon information and belief, the Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

304. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

305. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

H. Defendants Ignored Red Flags Of Abuse and Diversion

306. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database.[126] The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturing Defendants, but has not been disclosed to the public.

307. Yet, publicly available information confirms that Defendants funneled far more opioids into the Andover region than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Andover.

308. The Town's information and belief rests upon the following facts:

a. Distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances.

b. The Big Three and the Manufacturing Defendants regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens has direct access to the transaction data of its chain of retail pharmacies.

c. The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; (d) Walgreens has been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

d. Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens for their retail stores contributed to their failure. The result is both deeply troubling and entirely predictable: opioids flowed out of

[126] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

national retail pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

309. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

310. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to divert prescription opioids.[127] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

311. According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale

[127] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

312. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Andover, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

313. In addition, between 2010 and 2016, an average of 152.02mg of oxycodone were dispersed per Essex County resident.[128]

314. A former Mallinckrodt sales representative regularly visited Andover- area criminally indicted doctor, Fathallah Mashali, over the course of 5 years. During those visits the Mallinckrodt representative saw the doctor's office overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. Though the sales representative and his supervisor acknowledged not wanting Mallinckrodt to be connected to the doctor, they decided not to report the doctor.

315. Additionally, as recently as July 2019, an Andover pharmacy which specializes in workers compensation patients was placed under investigation by the Massachusetts Attorney General's Office regarding whether it properly dispensed controlled substances. According to DEA ARCOS data, the Injured Workers Pharmacy, which is a national mail-order pharmacy, was the largest recipient of opioid pills in Massachusetts from 2006 until 2012. During this time period,

[128] Public ARCOS data.

the pharmacy received 34.3 million opioid pills, which was almost three times more than the net biggest recipient of opioids in the Commonwealth.[129]

316. Upon information and belief, these providers and others like him and the pharmacies at which their patients filled their prescription for opioids, and The Injured Workers Pharmacy and others like it, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in the Andover area, but to specific instances of diversion. Yet, there is no indication that Defendants reported these doctors or pharmacies to law enforcement or medical or pharmacy boards.

317. Based upon these red flags, and the Distributor Defendants' ability to obtain dispensing information from its customers, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in and affecting Andover.

I. Defendants Hid Their Lack Of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

318. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

319. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they

[129]https://www.bostonglobe.com/business/2019/07/24/andover-pharmacy-under-investigation-for-opioid-dispensing/yBCeO3LE7WBq549RNVT9xN/story.html

sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

320. More generally, the Defendants publically portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[130] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[131] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[132] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and

[130] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[131] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[132] Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[133]

321. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[134] Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[135]

322. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." [136] A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[137]

323. Walgreens, too, publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through

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[133] Lenny Bernstein et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job', The Washington Post (Oct. 22,2016), http://wapo.st/2vCRGLt.

[134] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

[135] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[136] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[137] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

324. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[138]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

325. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

326. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

327. Manufacturing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. The Sackler Defendants serve as a hallmark

[138] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

example of such wrongful conduct. Purdue, deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[139]

328. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

329. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[140] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[141] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close

[139] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[140] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[141] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility/.

coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[142]

330. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

331. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

J. The Sackler Defendants are Personally Responsible for the Opioid Crisis in Andover

332. Defendants Richard Sackler, Kathe Sackler, David Sackler, Jonathan Sackler, Theresa Sackler, Ilene Sackler Lefcourt, Beverly Sackler, and Mortimer Sackler ("Sackler Defendants") each personally directed the unfair, deceptive and otherwise unlawful conduct alleged herein. In 1999, Richard Sackler became the CEO of Purdue, and Jonathan, Kathe and Mortimer were Vice Presidents of the Company.[143] Their actions were taken as members of the

[142] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

[143] 2000-03-26, Peter Healy, Opening the Medicine Chest: Purdue Pharma prepares to raise its profile, #24865.1.

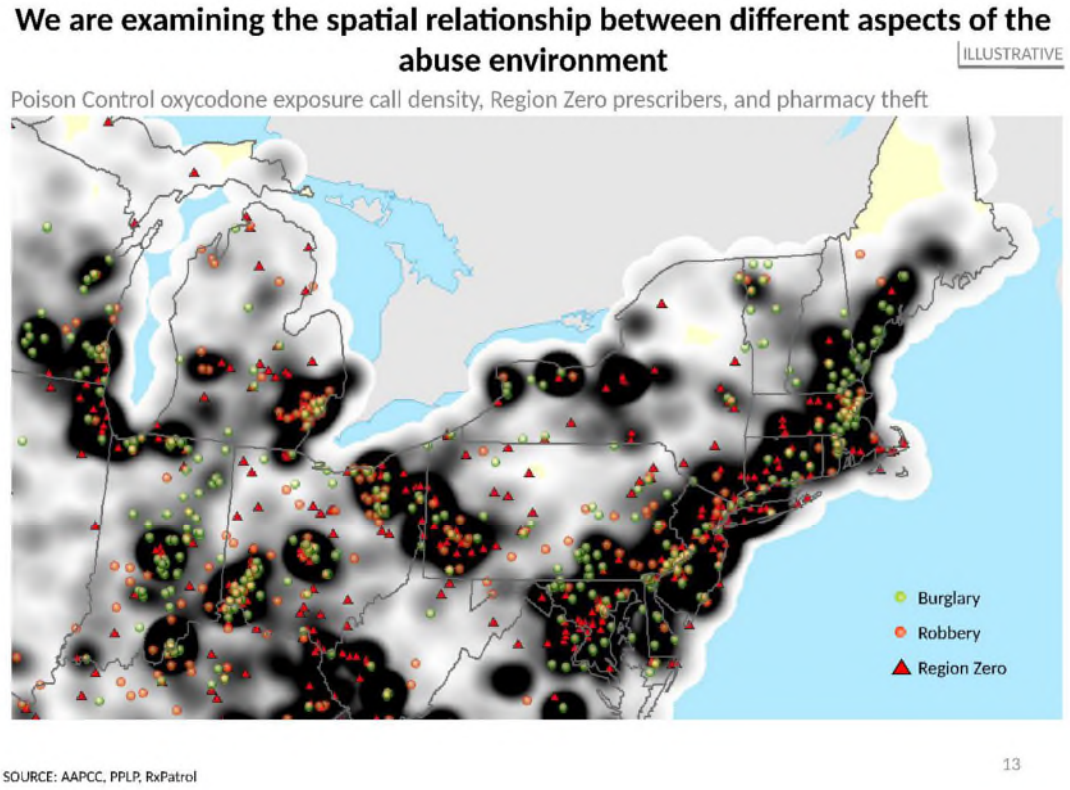
Purdue Board of Directors as well as individually as Purdue executive officers and owners of, as the company describes it, "the global Sackler pharmaceutical enterprise."

333. The Sacklers recognized the significant risk that Purdue's sales practices and impacts created for the company—and family—but nonetheless persisted in their involvement and in the company's misconduct.

1. The Sackler Defendants' actions as members of the Board

334. Purdue's Board of Directors is very hands-on, described in the company's own planning documents as "the 'de-facto' CEO." For events described below that occurred prior July 2012, the Sackler Defendants include Richard, Kathe, Jonathan, Mortimer, Beverly, Theresa, and Ilene Sackler Lefcourt. For events that occurred, after July 2012, the Sackler Defendants include all of the named Sackler Defendants.

335. The Board of Directors oversaw Purdue's compliance obligations, including implementation of Purdue's "Region Zero" program for identifying suspicious prescribers and pharmacies, which included prescribers and pharmacies in Delaware.



336. Defendant David Sackler acknowledged the problems of the "Region Zero" program, which included the fact that Purdue targeted doctors who lost their medical licenses due to over-prescribing. In June 2019, Defendant David Sackler even expressed his hesitation to place problematic doctors on the list. Specifically, when discussing "Region Zero" he stated, "[i]s it perfect?...Of course not. Far from it. The company made the best decisions it can with incredibly high stakes. It is life-ruining to accuse someone of diversion who isn't doing it."[144]

[144] https://www.vanityfair.com/news/2019/06/david-sackler-pleads-his-case-on-the-opioid-epidemic

337. As another example, in 2007 one of Purdue's top attorneys, Howard Udell, sent the Sackler Defendants an email about news stories around the country that showed DEA data that demonstrated large increases of the use of opioids, particularly OxyContin, from 1997 until 2005. According to the communication, he stated, "[m]any of these articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products." Instead of stopping or redressing the deceptive marketing, however, the response was a public relations campaign to counter the news reports and publicly promote Purdue as a good corporate citizen.

338. The Sackler Defendants, like other suppliers, had an obligation to report suspicious prescribers. Numerous examples show the Sacklers were aware of the abuse and diversion of OxyContin but took little meaningful action to address it. For example, as stated *supra*, of over 3,000 reports of concern, only 109 field inquiries were conducted in response. Purdue failed to report calls to the compliance hotline and the reports of concern to authorities.

339. The Sackler Defendants were longstanding members of Purdue's Board of Directors and controlled Purdue as owners. As such, they were informed of and approved the decisions related to Purdue's marketing and compliance operations that were at the core of Purdue's business. However, as laid out below, the Sackler Defendants exercised a level of involvement and control, particularly in the unlawful conduct described in this Complaint, which surpassed even that of other Board members. In addition, as also detailed below, each of the Sackler Defendants served for many years as executive officers of Purdue, taking many actions

personally to carry out the unfair, deceptive and otherwise unlawful activity that led to Andover's opioid epidemic.

340. According to planning documents prepared by Craig Landau, Purdue's CEO, the Purdue's Board was referred to as the "*de-facto*" CEOs. These *de-facto* CEOs also made sure that the formal CEO would remain loyal to their family and would not betray their confidence or undermine them.

341. Evidence shows that the Sackler Defendants were involved in Purdue's marketing. To ensure marketing consistency nationwide, Purdue, among other things, provided multi-week trainings for sales representatives at its headquarters in Connecticut, followed by field training in the target area with more seasoned representatives.[145] One representative recalled being seated at a table with Richard Sackler "[a]t a celebratory dinner following the training, and described himself as 'blown away,' thinking: 'This is the dude that made it happen. He has a company that his family owns. I want to *be* him one day.'"[146]

2. Richard Sackler

342. A blockbuster launch of OxyContin was particularly important to Defendant Richard Sackler because he knew that there would soon be generic competition for their other big earner, MS Contin. Accordingly, Defendant Richard Sackler personally oversaw, directed, made and approved many of the key decisions regarding Purdue's opioids and he is legally responsible for their outcomes in Andover.

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[145] Decl. of Sean Thatcher, *Montana v. Purdue Pharma L.P.*, No. ADV-2017-949 (Mont. 1st Jud. Dist. Ct., Lewis & Clark Cty.).

[146] Patrick Radden Keefe, *The Family that Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

343. Defendant Richard Sackler spent 43 years at Purdue in his various capacities, including the head of marketing, President, Co-Chairman of the Board, and Board member. Upon information and belief, as head of Purdue's marketing department and then President and Co-Chairman of Purdue's Board, with a demonstrated interest and involvement in Purdue's sales efforts and promotional messaging, Defendant Richard Sackler would have been aware of and approved all of Purdue's marketing themes and strategies.

344. Defendant Richard Sackler has been characterized in the press as having an "an appetite for micromanagement," including sending a middle of the night "sales bulletin," directing sales representatives to call his secretary with a "secret password."[147] A former employee recalled an "abrupt" shift as "Richard started taking a more prominent role in the company during the early 1980s.[148]

345. In March 2008 Defendant Richard Sackler sent the former VP of Sales, Russell Gasdia, an email with a list of seven sales questions, and copied Defendants Theresa, Jonathan, Mortimer, Kathe Sackler and Ilene Sackler Lefcourt. After having difficulty handling the pressure, Russell Gasdia wrote an email to the former CEO John Stewart and stated:

> John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.

346. Richard Sackler kept a particularly close eye on Purdue's sales numbers. In March 2008, for example, he directed staff to provide him with thousands of pieces of data about sales

[147] Christopher Glazek, *The Secretive Family Making Billions From The Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

[148] *Id.*

trends. Staff delivered the data early Sunday morning and Richard responded with detailed instructions for new data that he wanted that same day. Although an employee sent him the additional data only a few hours later, Richard Sackler responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard, highlighting issues with the results that Richard was looking for.

347. In August 2009, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that $200 million in profit was at stake.

348. In the wake of bad publicity regarding OxyContin diversion, overdoses, and deaths, Richard Sackler's solution was not to take responsibility and limit or correct Purdue's marketing, but to blame the victim. He wrote, confidentially, "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are the reckless criminals." By 2014, Purdue had changed its strategy and its message when it appeared that addiction treatment drugs may provide a business opportunity, stating: "[Addiction] can happen to anyone – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor."

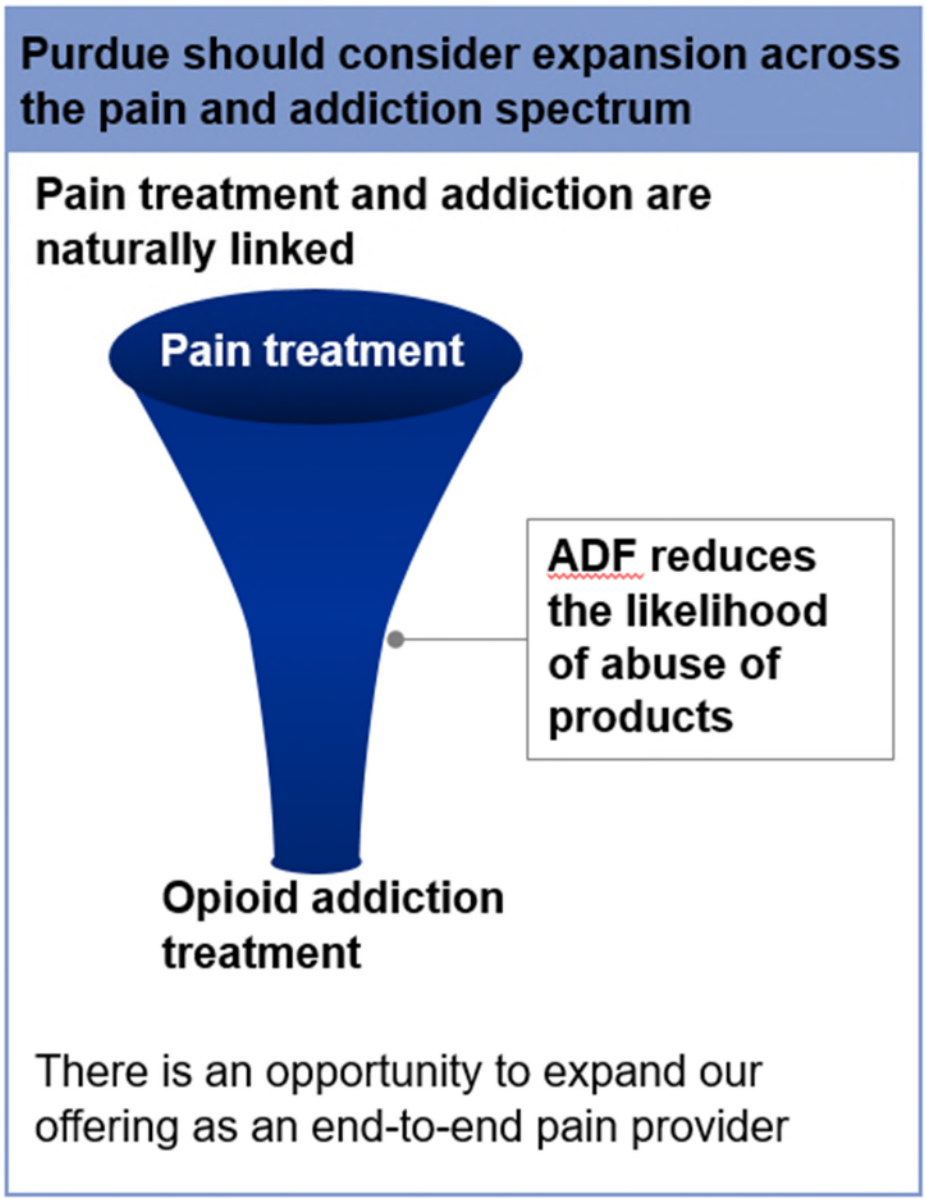
349. Despite Defendant Richard Sackler's lack of sensitivity regarding those who suffered from opioid abuse, misuse, and addiction, his son, Defendant David Sackler, protected his father's choice of words. Defendant David Sackler stated that at the time, his father was expressing concern that criminals were being confused with patients. However, Defendant

Richard Sackler's words of grouping those who suffer from addiction with "reckless criminals" spoke for themselves.

3. Kathe Sackler

350. In September 2014, Defendant Kathe Sackler was directly involved in a Purdue business development initiative dubbed "Project Tango," which explored a method by which Purdue could make profits not only from selling opioids, but also from treating resulting opioid addiction. Purdue identified stigmas and misperceptions regarding opioid abuse—stigmas and misperceptions Purdue had deliberately cultivated—as an impediment to success. Even so, Purdue recognized the enormous potential: "Opioid addiction (other than heroin) has grown by ~20% CAGR [compound annual growth rate] from 2000 to 2010."

351. The following graphic from a Purdue presentation on Project Tango visually demonstrates Purdue's *internal* acknowledgment of the link between pain treatment and opioid addiction treatment. Thus, entry into the opioid addiction treatment market was merely "an opportunity to expand [Purdue's] offering as an end-to-end pain provider."



352. Kathe Sackler did not pursue Project Tango. But Kathe Sackler, Richard Sackler and Purdue did not give up on this new strategy. Richard obtained the patent for an addiction treatment drug that he then transferred to Purdue. In true form, the Sackler Defendants are thus poised to further profit from the crisis they created.

4. Jonathan and Mortimer Sackler

353. Both Defendants Jonathan Sackler and Mortimer Sackler played significant roles on Purdue's Board. Defendant Mortimer Sackler joined Purdue in 1993, and remained on its Board until at least January 31, 2018. He was also the Vice President of Purdue from 1999 until 2003. Defendant Jonathan Sackler was a Purdue Board member from 1990 until at least 2018. Defendant Jonathan Sackler served as the Senior Vice President of Purdue from 2000 until 2003.

354. Additionally, in April 2014, Defendant Jonathan Sackler submitted a memorandum to Purdue's staff requiring that the Sacklers should receive "All Quarterly Reports and any other reports directed to the Board."

355. Further, Defendant Mortimer Sackler was among the recipients of a weekly distribution email list which sent detailed information about OxyContin performance in its sales category, as well as trends by a prescribing doctor's specialty, comparisons to competitors, and specific tracking of the highest-dosed OxyContin 80 mg sales. Defendant Jonathan Sackler also asked to be regularly informed about Purdue's opioids sales. In January 2012, he asked a staff member if he would resume a weekly or biweekly update on sales of one of Purdue's opioids, Butrans.

356. Defendant Mortimer Sackler wanted information regarding OxyContin's market share by strength in order to improve the sales of OxyContin. According to an email sent by Defendant Mortimer Sackler to the Sackler Defendants and Purdue's staff, he requested charts on the market share development and the "breakdown of OxyContin by market share by strength against competitions." Additionally, he stated, "I would like to understand more the recent dynamics of the market and where the patients are shifting to that we are losing. The staff responded the same day and explained that the "high dose prescriptions are declining," and "there are fewer patients titrating to the higher strengths from the lower ones."

357. Defendant Mortimer Sackler also expressed concerns about a two month period when Purdue sales representatives did not call on doctors. According to an internal email from February 2012, Defendant Mortimer Sackler was displeased about a national sales representatives meeting that was to be held near the holidays as it interfered with the sales representatives' visits to doctors. According to the email, he stated, "[w]ouldn't it be better to have the reps get back to work for January and back in front of doctors." He further stated that if Purdue rescheduled the meeting, "[A]t least then the doctors will have gotten at least one reminder visit from our reps in the last month where as now they might go two months without seeing one of our reps?"

5. David Sackler

358. Defendant David Sackler was a member of Purdue's Board from July 2012 until August 2018. He is currently a hedge fund manager for Moab Capital Partners, which he co-founded.

359. As a Board member, owner of Purdue, and son of Defendant Richard Sackler, Defendant David Sackler had special review of decisions that impacted both Purdue and the Sacklers. Defendant David Sackler agreed to send the recommendation to the outside Board members. Additionally, in the same email thread, Defendant David Sackler made high-level decisions regarding Purdue's spending on acquisitions and selling of Purdue's property. Thus as a Board member and owner, Defendant David Sackler was able to use his expertise as a hedge fund manager to control critical financial decisions for and on behalf of Purdue and his family.

360. Despite the overwhelming scientific evidence regarding abuse propensity of opioids such as OxyContin, David Sackler continues to deny the prevalence of opioid misuse, addiction and abuse. As recently as June 2019, in an interview with *Vanity Fair,* Defendant David Sackler insisted that the *New England Journal of Medicine* letter, discussed above, which states

that less than 1% of patients become addicted to opioids, is accurate. In the interview he pointed to an article on pain medication from Bonica's The Management of Pain, published six years before the release of OxyContin, which states that "narcotic addiction…occurs rarely, or not at all, in patients receiving narcotics for medical use." However, the material is sourced to the New England Journal of Medicine letter, and a recent study found that the letter created a pattern of "inaccurate citation," which "contributed to the North American opioid crisis."[149]

361. Additionally, like Defendant Mortimer Sackler, David Sackler has attempted to distinguish opioid abuse from addiction, and has done so publicly. In his *Vanity Fair* interview, David Sackler cited a review published in 2018 from the British Journal of Anesthesia, which states the rate of opioid addiction is 4.7 %, and claimed that this number may have overstated the risk of opioid addiction because "[t]hat number includes both abuse and dependence…[a]buse is addiction. Dependence has a very different definition. When you look at the studies that pull out the addiction piece of it, I think a fair number is somewhere between 2 and 3 %." However, the article cited by Defendant David Sackler is not based on actual evidence, but based solely on review of other studies. Dr. Andrew Kolodny M.D., cofounder of Physicians for Responsible Opioid Prescribing, stated none of the studies used in this article were designed to measure addiction in patients who took opioids on a long-term basis, which was the shift in treatment that Purdue, under the direction of the Sackler Defendants, created. According to Dr. Kolodny, "[j]ust about anyone who takes opioids for long enough, and at high enough doses, can get addicted."[150]

6. Theresa Sackler, Beverly Sackler, and Ilene Sackler Lefcourt

362. As Board members and owners, Defendants Theresa Sacker, Beverly Sackler, and

[149]https://www.vanityfair.com/news/2019/06/david-sackler-pleads-his-case-on-the-opioid-epidemic

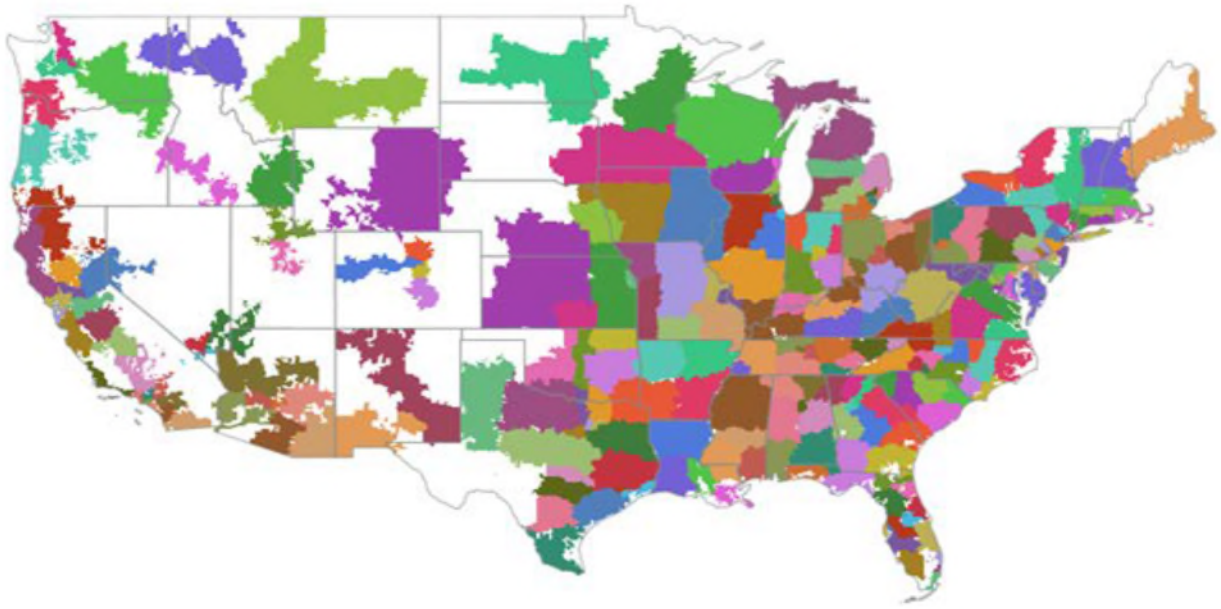
[150] *Id.*

Ilene Sackler Lefcourt were involved in strategic decision making and were kept apprised of the profits that Purdue's opioids brought the Sackler family.

363. For example, in May 2011, staff sent Defendant Theresa Sackler, along with Defendants Richard, Jonathan, Mortimer, and Kathe Sackler, a sales report on the tactics that sales representatives were using to push the sales of Butrans. The first tactic was focused on the select "core" of doctors Purdue believed would be most susceptible to Purdue sales representatives lobbying to prescribe more opioids. The second tactic was the "positioning of Butrans for specific patient types." Upon information and belief, "specific patient types" referred to elderly patients with arthritis. The third tactic was getting prescribers to commit to prescribing Butrans to specific patients. Defendant Jonathan Sackler did not think that these tactics were enough to increase Butrans' sales, and wrote to then-CEO John Stewart, "[t]his is starting to get ugly. Let's talk."

364. Additionally, in May 2011, staff told the Sackler Defendants that per the Sackler Defendants' orders, they had hired an additional 47 sales representatives to market their opioids. The Sackler Defendants were also told by staff that Purdue had employed 639 sales representatives and had visited prescribers 173,647 times in the first Quarter of 2011. Upon information and belief, these visits would have included Andover area prescribers.

365. In November 2017, Defendants Ilene Sackler Lefcourt, Theresa Sackler, Richard Sackler, Mortimer Sackler, Jonathan Sackler, David Sackler and Kathe Sackler, voted to decrease the sales force from 582 sales representatives to 302 sales representatives. Upon information and belief, these Defendants were aware that the sales representatives were continuing to promote and market opioids in Andover. Purdue's staff also provided these Defendants with a map of where sales representatives continued to detail doctors, which, upon information and belief, included the Andover area.



In February 2018, these Defendants voted to lay off 300 sales representatives.

366. Theresa Sackler, Beverly Sackler, and Ilene Sackler Lefcourt were aware of the diversion problems of the reformulated OxyContin. In May 2015, the staff told the Sackler Defendants that an independent non-profit concluded that reformulated OxyContin was not a cost-effective way to prevent opioid abuse. Defendant Theresa Sackler pushed back at this information, and asked the staff what they were doing to convince doctors and patients to continue using the opioid, despite having knowledge that it was not preventing abuse.

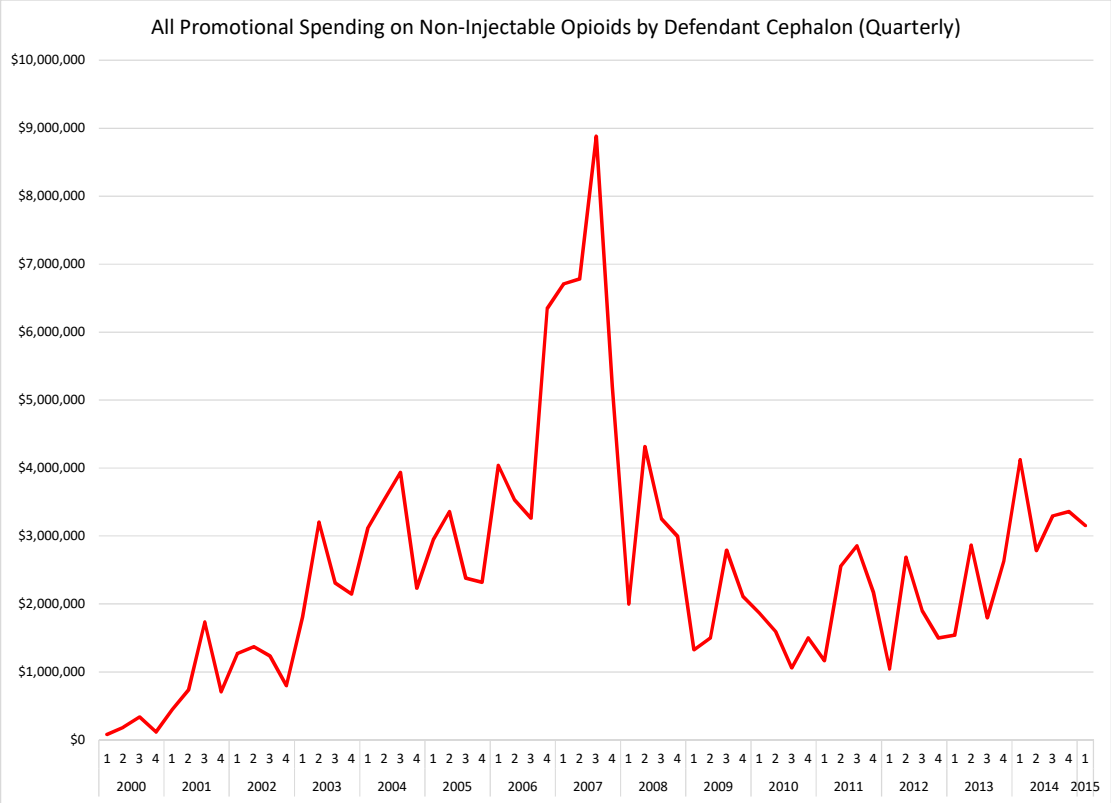
K. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed Andover and its Residents

367. Manufacturing Defendants' misrepresentations prompted Andover health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, Manufacturing Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in Massachusetts.

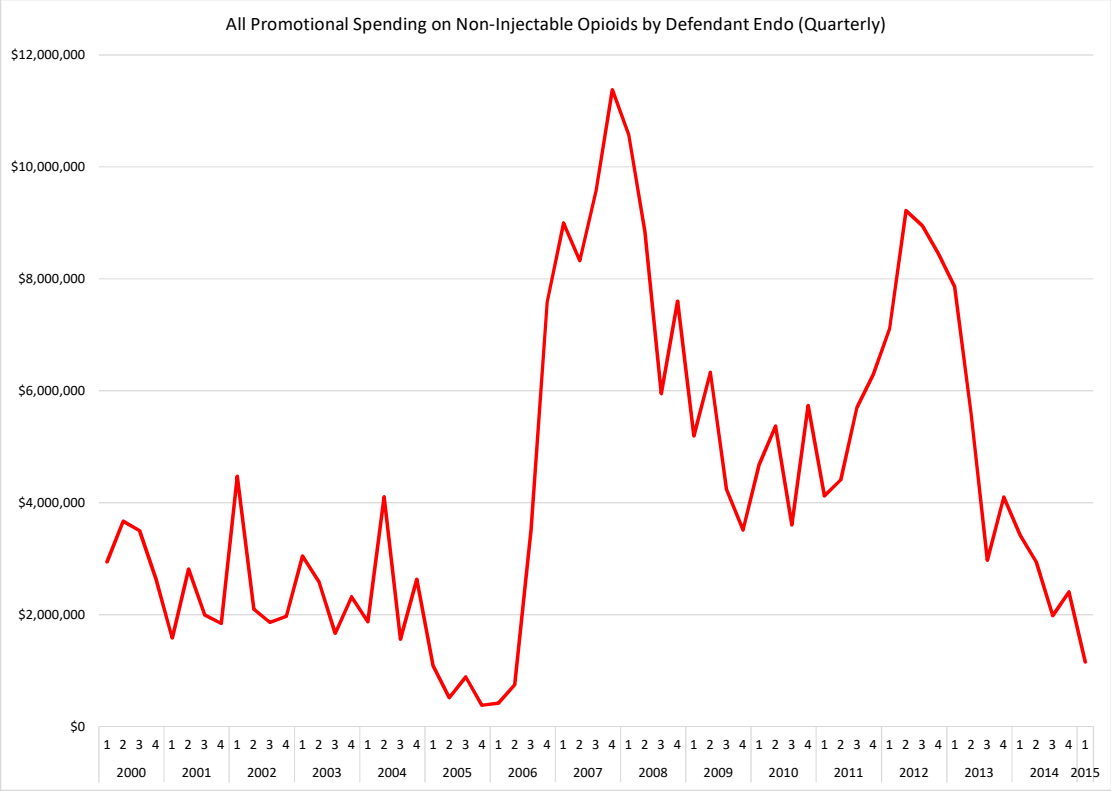
368. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

369. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, upon information and belief under the direction of the Sackler Defendants, $34 million by Janssen, $13 million by Teva, and $10 million by Endo, and $2 million by Actavis. .

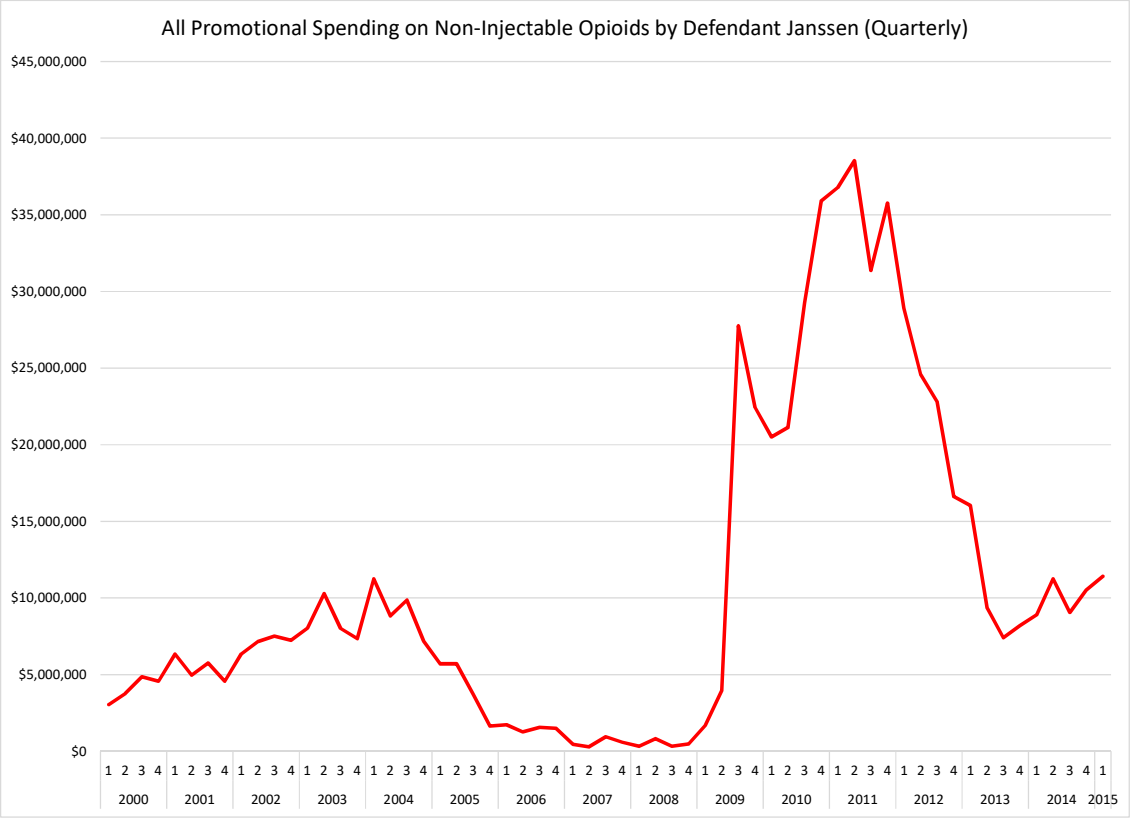
370. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



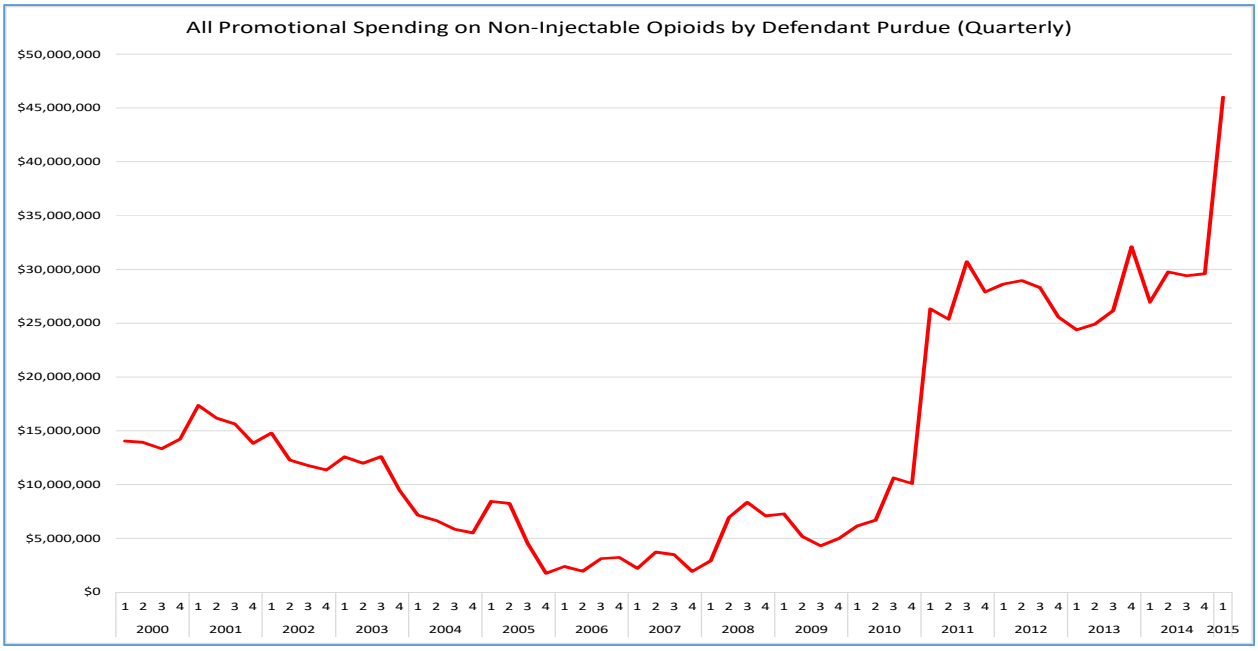
371. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



372. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



373. Purdue's, upon information and belief under the direction of the Sackler Defendants, quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise through at least 2015, as shown below:



374. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Andover. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[151]

[151] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

375. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[152]

376. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

377. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the

[152] *See* Murthy, *supra* note 2.

CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[153]

378. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[154]

379. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[155] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[156]

380. From fiscal year 2011 until fiscal year 2020, there were 139 opioid-related overdoses reported in Andover. Andover residents are working to help save those who suffer from overdoses. In 2017, an Andover electrician created a restroom alarm system that alerts people when someone suffers from an overdose. After spending 4 months researching a design that would help the problem of overdosing in the Boston Health Care for the Homeless Program's bathroom, the electrical contractor, John King, created a reverse motion detector that alerts the organization's security when the bathroom occupant does not move for two minutes. The alarm goes off several times a week, and alerts the security when someone has collapsed and stopped moving in the

[153] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

[154] Theodore J. Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[155] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[156] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Engl. J. Med. (Apr. 14, 2016).

restroom. The security personnel then calls the organization's clinical staff to administer Narcan to the individual. From the time the alarm was installed in March 2017 until at least November 2017, there were no reported deaths from the bathroom.[157]

381. Nationwide, opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses. Andover has experienced deaths related to opioids first-hand. In 2013, the Town had 4 opioid-related deaths. In 2014, this number increased to 6 deaths. From 2013 until 2017, there were a total of 21 opioid-related deaths in Andover.[158]

382. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. First responders in Andover have used Narcan to assist with reversal of opioid-related overdoses. In January 2019, police in Andover administrated Narcan to a 35 year-old man who suffered from an overdose at a local hotel, and was taken to a near-by hospital.

383. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25%

[157] https://www.eagletribune.com/heroin_epidemic/andover-electrician-designs-restroom-alarm-to-help-prevent-opioid-ods/article_0e60e128-cad3-11e7-b507-33b7c0fa4c70.html

[158] https://www.mass.gov/files/documents/2019/02/12/Opioid-related-Overdose-Deaths-by-City-Town-February-2019.pdf

of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

384. The abuse of opioids causes additional medical conditions as well. A growing number of people need medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the *Washington Post*, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

385. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse. Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin. However, according to the CDC Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries.

386. Children in Andover have experienced the dangers of opioids. In February 2016, the Andover school district began placing Narcan in every school within the district, from Pre-K to high school, out of concerns for opioid-related overdoses among students. In October 2015, students from Andover High School took an anonymous survey about drug use. Three out of 240 Andover students admitted to using opioids to get high. The Director of Nurses for Andover schools stated that the "average span of an overdose patient in Andover has broadened since 2014… In 2014, victims were between 18 and 55. In 2015, they were between 17 and 67 years

old. You can see that the span in age is getting broadened and certainly into the school-aged population."[159] Additionally, in December of 2018, an Andover teenager received an administration of Narcan at an Andover high school. The student, age 16 at the time, was in a school office alone for a short-period of time, and then was found in a "semi-conscious" state by a school employee. The school nurse administered two doses of Narcan, but it was unclear if the student suffered from an opioid-overdose. She was then taken to a local hospital for recovery.[160]

387. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. In 2013, an Andover-area hospital saw an average of 59 cases of NAS per 1,000 births, which was more than triple the state average that year.

[159]https://www.andovertownsman.com/news/local_news/andover-schools-to-stock-narcan/article_dfc69623-9c56-5d0d-8788-675a70ce2582.html

[160]https://www.eagletribune.com/news/merrimack_valley/narcan-administered-to-glts-student/article_310823ab-d4b4-52a4-9011-f3dd15455f9e.html

388. In addition, an increasing number of children in the Andover region have entered into foster care because their parents or caregivers are addicted to opioids. A couple who were both nurses in a near-by- hospital neonatal intensive care units have fostered 16 children, most of whom who were born with drug exposure. The couple has noticed an increase in orphaned and sickened babies born in area hospitals due to the opioid-crisis, and that many babies born in the NICU who suffer from NAS wait for weeks and even months for a foster family.

389. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury.

390. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

391. Those who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. The heroin epidemic has directly impacted Andover. In August 2018, a federal agents broke up a drug deal in North Andover worth over $500,000 which included four kilograms of heroin, five kilograms of fentanyl, 5,000 pills. The agents raided a warehouse and arrested an individual and in addition to the fentanyl, heroin, and pills found two bricks of either fentanyl or heroin.[161]

392. Fentanyl is a relatively recent, even more deadly problem stemming from the prescription opioid epidemic. Fentanyl—a powerful opioid prescribed for cancer pain or in

[161] https://www.masslive.com/news/2018/08/feds_seize_11_kilos_of_heroin.html

hospital settings that, in synthetic form, has made its way into communities across the country. In 2018, Massachusetts health officials announced that 90% of Massachusetts residents who died of drug overdoses had fentanyl in their systems. Additionally, fentanyl surpassed heroin as the leading cause of overdose deaths in the Commonwealth.[162] As recently as January 2019, an individual was arrested for selling fentanyl in the restroom of a North Andover mall. The man arrested for selling the fentanyl has allegedly sold drugs out of this restroom, a public area occupied by Andover residents, in the past. During the search incident to arrest, police found 94 grams of fentanyl on the individual, and a search of his home lead to the seizure of over 294 grams of fentanyl among other drugs.[163]

393. Andover has experienced intense crime due to the opioid epidemic. In August of 2016, three men were arrested in Andover and charged with trafficking 3,000 grams of heroin with a street value of approximately $210,000. Recently, while reflecting on the opioids crisis, the Andover Police Chief Patrick Keefe told officers that police would never be able to "arrest [themselves] out of this [opioid] problem," which is a telling sign of the growth of the opioid epidemic in Andover.[164] Additionally, the Town's police department has arrested hundreds of individuals in connection with the opioid crisis. In fiscal year 2013, the police department arrested 21 individuals related to opioids. In 2014, this number nearly tripled to 61. In 2015, this number increased to 91 opioids related to opioids. In total, the Andover police department arrested 466 individuals for opioid-related arrests from fiscal year 2011 until fiscal year 2020.

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[162] Id.

[163] https://www.bostonglobe.com/metro/2019/01/18/north-andover-police-arrest-alleged-dealer-and-customer-restroom-fentanyl-drug-bust/Nie3e8JGHH8sDtp35DK4sK/story.html

[164] https://www.andovertownsman.com/editorials/something-working-in-fight-against-opioids/article_98f0fdf6-638f-56cc-81c1-ba2d92ce0c4b.html

394. In light of this crippling epidemic, Andover has instituted a number of cutting edge programs aimed at curbing addiction and abuse. For example, the Town Meeting approved funding for an outreach counselor to work within the town. This counselor is based at the police station, and conducts outreach and attempts to connect those who suffer from opioid abuse disorder with treatment and assistance.[165]

395. Andover has incurred great expenses and has spent significant funds on fighting the opioid epidemic within the Town. For example, from fiscal year 2011 until fiscal year 2020, the town has spent nearly $500,000 on costs to curb the opioid epidemic. The Town's spending includes costs related to Narcan, and the salary and benefits for a Community Support Coordinator.

L. Defendants Fraudulently Concealed Their Misconduct

396. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and

[165] https://www.andovertownsman.com/editorials/something-working-in-fight-against-opioids/article_98f0fdf6-638f-56cc-81c1-ba2d92ce0c4b.html

CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

397. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue, Endo, Teva, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

398. Manufacturing Defendants thus successfully concealed from the medical community, patients, and Andover facts sufficient to arouse suspicion of the claims that Andover now asserts. Andover did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

399. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

400. Defendants thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the Town now asserts. The Town

did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

401. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

V. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

402. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[166] formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

403. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" (APF, AAPM, APS, and FSMB) and KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman) described herein. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial

[166] The RICO Marketing Defendants referred to in this section are those named in Count VI under 28 U.S.C. § 1961 *et seq.* - Teva, Janssen, and Endo.

financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

404. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named "pseudoaddiction;" (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

405. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

406. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information is shared, misrepresentations are coordinated, and

payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

407. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

408. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of

consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

409. As public scrutiny and media coverage focused on how opioids ravaged communities in Massachusetts and throughout the United States, the Front Groups and KOLs did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

410. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

411. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

412. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

413. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

414. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

415. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the Andover area and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's health care and law enforcement systems.

416. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

417. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation

or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants

suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiffs and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

418. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and Massachusetts. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

419. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

420. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[167] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[168]

[167] *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

[168] *Id*. 2.

421. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the Marketing Defendants.

422. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The Opioid Marketing Enterprise Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

423. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, and Alliance for Patient Access. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing

Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

424. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

425. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

426. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketing activity as described herein.

427. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiffs' reliance on the Marketing Defendants' misrepresentations.

428. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity,

through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Massachusetts consumers, the State, and other intended victims.

429. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use of these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

430. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiffs, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

431. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

432. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

433. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding

the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

434. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

435. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

436. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

437. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[169] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain

[169] http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited, Apr. 21, 2018).

Defendants" (all Defendants other than Walgreens, and Janssen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

438. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate with within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

439. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[170] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute -- there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

[170] 21 C.F.R. 1301.74(b).

440. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

441. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between

proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

442. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

443. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

444. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

445. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[171]

446. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

447. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion

[171] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

448. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

449. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

450. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

451. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

452. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
Teva	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd.,	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	**Chemical Name**	**CSA Schedule**
	(3) Teva Pharmaceuticals USA, Inc.	Generic oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt PLC*)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

453. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

454. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

455. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

456. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

457. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

458. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

459. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

460. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

461. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

462. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

463. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The

sheer volume of enforcement actions against the Supply Chain Defendants supports this conclusion that the Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

464. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiffs' Community and the Plaintiffs. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiffs. The RICO Supply Chain Defendants were aware that Plaintiffs and the citizens of these jurisdictions rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

465. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

VI. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

466. The Town incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

467. Each Defendant is liable for public nuisance because its conduct has caused an unreasonable and substantial interference with a right common to the general public, which is the

proximate cause of, and/or substantial factor leading to, the Town's injury. *See* Restatement Second, Torts §821B.

468. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and/or other fraudulent schemes as described herein, created and maintained the opioid epidemic in and affecting the Town of Andover, which is harmful and disruptive to and unreasonably annoys, injures, endangers, and interferes with the public health, public safety, public peace, public comfort, and/or public convenience. The public nuisance caused by Defendants has significantly harmed the Town and a considerable number of its residents.

469. The Marketing Defendants fraudulently and deceptively marketed opioids. Further, Defendant Purdue misleadingly portrayed itself as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, it failed to satisfy even the minimum, legally-required obligations to report suspicious prescribers.

470. In addition, by causing dangerously addictive drugs to flood the community, and to be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of Andover to public health, safety, peace, comfort, and convenience. The public nuisance caused by Defendants' actions has caused substantial annoyance, inconvenience, and injury to the public.

471. By distributing and selling dangerously addictive opioid drugs not connected to a legitimate medical, scientific, or industrial purpose, all Defendants have committed a course of conduct that injuriously affects the safety, healthy, and morals of the people of Andover.

472. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes and by failing to report suspicious orders of opioids, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of Andover.

473. Defendants knowingly, intentionally, unlawfully, recklessly, and fraudulently manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will produce widespread distribution of prescription opioids in and/or to the Andover area, resulting in addiction and abuse, an elevated level of crime, death, and injuries to the residents of Andover, a higher level of fear, discomfort, and inconvenience to the residents of Andover, and direct costs to Andover.

474. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in the Town. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted.

475. Defendants knew of the public health hazard their conduct would create.

476. It was foreseeable to Defendants that their conduct would unreasonably interfere with the public health, public safety, public peace, public comfort, and/or public convenience.

477. Defendants' conduct is unreasonable, intentional, unlawful, reckless, or negligent.

478. Defendants' conduct is widespread and persistent, and creates substantial and ongoing harm. The harm inflicted outweighs any offsetting benefit. Defendants' conduct has

caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety. Defendants' ongoing and persistent misconduct is producing permanent and long-lasting damage.

479. Defendants had control over their conduct in the Andover area as is described in this Complaint, and that conduct has had an adverse effect on the public. Defendants had sufficient control over, and responsibility for, the public nuisance they created—Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of marketing, promotion, distribution, and creation and maintenance of the demand for prescription opioids at all relevant times.

480. Defendants' conduct and the opioid epidemic it created is likely to continue to cause significant harm to the Town and its residents.

481. The Town has suffered and continue to suffer special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred and continues to incur substantial costs from investigating, monitoring, policing, and remediating the opioid epidemic.

482. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Town alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

483. The public nuisance – i.e. the opioid epidemic - created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

WHEREFORE, the Town demands judgment in their favor against the Defendants for injunctive relief, abatement of the public nuisance, and for compensatory damages in an amount to be determined by a jury, together with prejudgment interest, post-judgment interest, costs and

expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Violations of Massachusetts General Laws
Chapter 93A
(Against All Defendants)

484. The Town incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

485. Through the acts alleged herein Defendants engaged in deceptive trade practices in violation of Massachusetts law.

486. Defendants were and still are engaged in "trade" and "commerce" as defined by M.G.L. c. 93A, § 1.

487. Plaintiff was and is engaged in "trade" and "commerce" as defined by M.G.L. c. 93A, § 1.

488. The transactions, actions and inaction of Defendants, as described herein, constitutes unfair and deceptive acts and practices as defined by, and in violation of, M.G.L. c. 93A, §§ 2 and 11.

489. Defendants committed and continue to commit repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce.

490. Each Defendant wrongfully represented that the opioid prescriptions they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have. These misrepresentations include but are not limited to the following:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

d. Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

e. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

f. Defendants' claims that screening tools effectively prevent addiction;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

k. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

l. Defendants' use of front groups to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

491. The Defendants used exaggeration and/or ambiguity as to material facts and omitted and concealed material facts, which tended to deceive and/or did in fact deceive. The omissions and concealments of material fact include but are not limited to the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

e. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue's and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease, and may increase overall abuse; and

h. Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

492. The Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

493. In addition, each Manufacturer and Distributor Defendant engaged in unfair and/or deceptive trade practices by failing to report suspicious orders of opioids and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

494. Defendants failed to disclose the material facts that, *inter alia,* they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell or distribute opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

495. Defendants' unfair, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the public, the healthcare community, and the Town's communities.

496. Defendants acted knowingly, intentionally, and unlawfully.

497. Defendants' representations, concealments, and omissions constitute a willful course of conduct that continues to this day.

498. Without Defendants' unfair and/or deceptive trade practices, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted. Defendants' actions were immoral, unethical and unscrupulous and unlawfully caused the opioid epidemic in Massachusetts and in and affecting Andover.

499. Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in the Town. Each Defendant had a nondelegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate channels.

500. The damages that the Town seeks to recover were sustained as a direct and proximate result of the Defendants' intentional and unlawful acts and omissions.

501. The Town seeks injunctive relief and economic losses resulting from Defendants' deceptive trade practices. The Town does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

502. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Town alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Town demands judgment against the Defendants in an amount to be determined at trial, with said amount doubled or trebled in accordance with the provisions of Chapter 93A; and, that said judgment include an award of attorney's fees and costs; and for such other relief as this Court deems just and equitable.

COUNT III
Negligence and Negligent Misrepresentation
(Against All Defendants)

503. The Town incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

504. To establish actionable negligence, the Town must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom. All such elements exist here.

505. Defendants have a duty to exercise reasonable care in manufacturing, marketing, distributing, and selling highly dangerous opioid drugs.

506. Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

507. Manufacturing Defendants repeatedly breached their duties by deceptively marketing opioids as described herein, including minimizing their risks, such as the risks of addiction and overdose, and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain. Manufacturing Defendants omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. These Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

508. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by

failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the purpose of these duties was to prevent the resulting harm – misuse and/or diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

509. The Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to the Andover area and destinations from which they knew opioids were likely to be diverted into Andover, in addition to other misrepresentations alleged and incorporated herein.

510. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

511. Defendants breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

512. The foreseeable harm from a breach of these duties is the abuse and diversion of prescription opioids, and addiction, overdose, and death in the Town's communities.

513. Reasonably prudent manufacturers of pharmaceutical products would know that deceptively and misleadingly marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants. Reasonably prudent manufacturers and distributors would know that failing to report suspicious orders and prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

514. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances, such as opioids, and preventing diversion and abuse.

515. These Defendants' breach of the duties described herein directly and proximately resulted in the injuries and damages alleged by the Town.

516. The Town seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. It does not seek damages which may have been suffered by individual citizens of the Town for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants

517. The misconduct alleged in this case is ongoing and persistent.

518. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Town alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Town demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IV
Fraud and Fraudulent Misrepresentation
(Against All Defendants)

519. The Town incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

520. Defendants, individually and acting through their employees and agents, knowingly and intentionally made misrepresentations and omissions of facts material to the Town, and its residents and medical professionals to induce them to purchase, administer, and consume opioids as set forth in detail above.

521. Manufacturing Defendants' fraudulent misrepresentations are detailed in this Complaint and include overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; falsely promoting abuse-deterrent formulations as reducing abuse; falsely claiming that OxyContin provides 12 hours of relief; and falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids.

522. Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead Town prescribers and consumers.

523. All Defendants made false statements regarding their compliance with state and federal law regarding their duties to monitor, report, and halt suspicious orders and to prevent diversion, and/or they concealed their noncompliance with these requirements.

524. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

525. Defendants knew or should have known that the Town would be adversely impacted economically by their misrepresentations in that citizens of the Town would become addicted to the Defendants' opioids which, in turn, would cause the Town to expend funds on emergency response; law enforcement, social services, and other municipal services to care for their citizens, thereby proximately causing the Town injuries and damages. As such, the Defendants owed a duty of care to the Town.

526. Defendants' false representations and concealments were reasonably calculated to deceive the Town and its residents and the physicians who prescribed and the patients who took opioids in the Town, were made with the intent to deceive, and did in fact deceive these persons and the Town.

527. Defendants intended for the Town, its residents, and health care providers to rely on their misrepresentations and omissions, and knew that such reliance would cause the Town to suffer loss.

528. The Town and healthcare providers and residents in the Town reasonably relied on Defendants' misrepresentations and omissions in writing, filling, using, and paying for prescriptions for Defendants' opioids. As a result of Defendants' fraudulent misrepresentations, the use of Defendants' opioid medicines became widespread and continuous, and resulted in the scourge of addiction, overdose, and death that is plaguing the country and the Town.

529. The Town suffered actual pecuniary damages proximately caused by Defendants' misrepresentations and omissions of material fact, which include expending additional funds on emergency response, law enforcement, social services, and other municipal services that the Town otherwise would not have incurred.

530. The Town seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the fraud of Defendants. It does not seek damages which may have been suffered by individual citizens of the Town for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

531. The fraud alleged in this case is ongoing and persistent.

532. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Town alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, the Town demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT V
Unjust Enrichment
(Against All Defendants)

533. The Town incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

534. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the Town, including from opioids foreseeably and deliberately diverted within and into the Town.

535. The Town has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

536. These expenditures include the provision of healthcare services and benefits, emergency services, social services, and other services in excess of what would normally be provided were it not for the opioid epidemic.

537. These expenditures have helped sustain Defendants' businesses.

538. The Town has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing practices.

539. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

540. The Town has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids and improper and excessive distribution of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the Town lacks a remedy provided by law.

541. Defendants have unjustly retained benefits to the detriment of the Town, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

542. Defendants' misconduct alleged in this case is ongoing and persistent.

543. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The Town alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

544. The Town has incurred expenditures for special programs over and above its ordinary public services.

WHEREFORE, the Town seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

COUNT VI
Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Marketing Enterprise
(Against Teva, Janssen, and Endo (the "RICO Marketing Defendants"))

545. The Town incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

546. The RICO Marketing Defendants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' scheme; through CME programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called "KOLs" who were paid by the RICO Marketing Defendants to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine

false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

547. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Teva, Janssen, and Endo); the Front Groups (APF, AAPM, APS, and FSMB); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

548. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

549. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

550. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false messages.

551. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendants' false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

552. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

553. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

554. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

555. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

556. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution

channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

557. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

558. The RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

559. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, the Town has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated

misrepresentations and false statements to Andover area consumers, prescribers, and regulators, and how those acts were in furtherance of the scheme.

560. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Andover area consumers, prescribers, regulators and The Town. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

561. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

562. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

563. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Andover area consumers, prescribers, regulators and the Town. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Andover consumers, prescribers, regulators and

the Town. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

564. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

565. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

566. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

567. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Town injury in their business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. The Town's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as the Town alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Marketing Defendants

engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

568. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.

569. Specifically, the RICO Marketing Defendants' creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured the Town in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Andover's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include but are not limited to:

a. Losses caused by the decrease in funding available for the Town's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs of training emergency and/or first responders in the proper handling of drugs such as fentanyl, and the proper treatment of drug overdoses;

c. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

e. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population; and

f. Costs associated with Town educational programs and support groups related to the opioid epidemic.

570. The Town's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of The Town's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, the Town would not have lost money or property.

571. Andover is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

WHEREFORE, the Town seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

COUNT VII
Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Supply Chain Enterprise
(Against Teva, Endo, Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants"))

572. The Town incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

573. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

574. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

575. The RICO Supply Chain Defendants were members the Healthcare Distribution Alliance (the "HDA"). Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

576. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

577. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

578. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity

that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

579. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

580. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

581. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

a. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to: Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The Distribution Defendants violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

582. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

583. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

584. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

585. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

586. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

587. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

588. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Town's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

589. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

590. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

591. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants'

books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

592. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

593. It was foreseeable to Defendants that the Town would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

594. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

595. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Town's injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably caused an opioid epidemic. Andover was injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

596. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception,

that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.

597. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Andover in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

598. Specifically, the Town's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include but are not limited to:

a. Losses caused by the decrease in funding available for the Town's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs of training emergency and/or first responders in the proper handling of drugs such as fentanyl, and the proper treatment of drug overdoses;

c. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

e. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population; and

f. Costs associated with Town educational programs and support groups related to the opioid epidemic.

599. Andover injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of the Town's injuries. But for

the opioid-addiction epidemic created by Defendants' conduct, the Town would not have lost money or property.

600. The Town's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

601. The Town is most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

WHEREFORE, the Town seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

VII. PRAYER FOR RELIEF

WHEREFORE, the Town requests the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate and pay damages for the public nuisance;

D. A finding that Defendants engaged in unfair and deceptive trade practices in violation of M.G.L. c. 93A, §§ 2 and 11;

E. A finding that by the acts alleged herein, the Defendants were negligent and grossly negligent, and that Defendants engaged in fraudulent misrepresentations;

F. Compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

G. Punitive damages;

H. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

I. Treble or multiple damages and civil penalties as allowed by statute;

J. For costs, filing fees, pre and post judgment interest, and attorney's fees; and;

K. For all other relief at law or in equity, deemed just by this Court.

PLAINTIFF DEMANDS A TRIAL BY JURY AS TO ALL ISSUES SO TRIABLE.

Respectfully submitted,

TOWN OF ANDOVER
By its attorneys,

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** Pro hac vice applications to be submitted.*